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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/565,452	05/05/2006	Hengyuan Lang	34056-US-PCT	9887	
	75074 7590 04/14/2009 NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.			EXAMINER	
220 MASSACHUSETTS AVENUE			WILLIS, DOUGLAS M		
CAMBRIDGE, MA 02139			ART UNIT	PAPER NUMBER	
		1624			
			MAIL DATE	DELIVERY MODE	
			04/14/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/565,452	LANG ET AL.				
Office Action Summary	Examiner	Art Unit				
	DOUGLAS M. WILLIS	1624				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	<b>J.</b> nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>05 Ma</u>	arch 2009					
•	•					
3) Since this application is in condition for allowan		secution as to the merits is				
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-3,5-10,12,20,21,23-27,29,31,32,34-39 and 54</u> is/are pending in the application.						
4a) Of the above claim(s) <u>6-10, 38 and 39</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-3,5,12,20,21,23-27,29,31,32,34-37 and 54</u> is/are rejected.						
7) Claim(s) is/are objected to.						
· · · · ·						
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)  All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal P					
3) ☑ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>01-20-06; 02-27-09</u> .	6) Other:	atent Application				
<del></del>						

#### **DETAILED ACTION**

## Status of the Claims / Priority

Claims 1-3, 5-10, 12, 20, 21, 23-27, 29, 31, 32, 34-39 and 54 are pending in the current application. According to the *Amendments to the Claims*, filed March 5, 2009, claims 1, 2, 5, 34 and 37 were amended and claims 4, 11, 13-19, 22, 28, 30, 33, 40-53 and 55-61 were canceled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/US2004/023726, filed July 23, 2004, which claims priority under 35 U.S.C. § 119(e) to US Provisional Application No. 60/490,096, filed July 25, 2003.

Currently, Group II, claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-37 and 54, drawn to substituted benzenes and pharmaceutical compositions of the formula (I), is constructively elected by original presentation for prosecution on the merits. Consequently, claim 27, withdrawn from further consideration, according to the *Amendments to the Claims*, filed March 5, 2009, is hereby rejoined for the second Office and prosecution on the merits. See MPEP § 821.03.

Appropriate correction of the claim status identifier is required in response to this Office action. See 37 CFR 1.121 and MPEP § 714.

## Status of Restrictions / Election of Species

Applicant's affirmation of the following election, without traverse, in the reply filed on

 $(R^2)$ 

March 5, 2009, is acknowledged: Group II - claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-37 and 54, where  $Y = -L-R^3$ , wherein L = -C(=O)NH or -NH(C=O); and

X = -phenyl, -pyridinyl or -pyrimidinyl; and b) substituted benzene of formula (I) - p. 33,

example 1.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 6-10, 38 and 39, drawn to nonelected inventions, without traverse, in the reply filed on March 5, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Thus, a second Office action and prosecution on the merits of claims 11-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-37 and 54 is contained within.

# Status of Information Disclosure Statement Objection - Foreign References

Applicant's arguments, on page 9 of the *Remarks*, filed March 5, 2009, with respect to the information disclosure statement, have been fully considered, but are not persuasive. Consequently, the objection to the information disclosure statement, made in the *Non-Final Rejection*, mailed on December 5, 2008, is maintained for the reasons of record.

### Status of Specification Objection - Disclosure

Applicant's arguments, on page 9 of the *Remarks*, filed March 5, 2009, with respect to the objection to the specification of the disclosure, have been fully considered and are persuasive. Consequently, the objection to the specification of the disclosure, made in the *Non-Final Rejection*, mailed on December 5, 2008, is hereby withdrawn, since, according to the *Amendments to the Specification*, filed March 5, 2009, the specification of the disclosure has been amended to overcome the objection.

# Status of Specification Objection - Title

Applicant's arguments, on page 9 of the *Remarks*, filed March 5, 2009, with respect to the objection to the title of the invention, have been fully considered and are persuasive. Consequently, the objection to the title of the invention, made in the *Non-Final Rejection*, mailed on December 5, 2008, is hereby withdrawn, since, according to the *Amendments to the Title*, filed March 5, 2009, the title of the invention has been amended to overcome the objection.

## Status of Specification Objection - Abstract

Applicant's arguments, on page 9 of the *Remarks*, filed March 5, 2009, with respect to the objection to the abstract of the disclosure, have been fully considered, but are not persuasive. Consequently, the objection to the abstract of the disclosure, made in the *Non-Final Rejection*, mailed on December 5, 2008, is maintained for the reasons of record.

The abstract of the disclosure is objected to because: a) it neither provides for the general nature of the compounds, nor exemplifies any members or formulae illustrative of its class; and b) *X* and *Y* should be amended to reflect the scope of the *Requirement for Restriction / Election of Species*, mailed on May 16, 2008, and stated herein above in the section entitled *Status of Restrictions / Election of Species*. Correction is required. See MPEP § 608.01(b).

# Status of Claim Objections

Applicant's arguments, on page 9 of the *Remarks*, filed March 5, 2009, with respect to claims 55 and 57, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 55 and 57 have been canceled by applicant.

Applicant's arguments, on page 9 of the *Remarks*, filed March 5, 2009, with respect to claims 1, 5 and 34, have been fully considered and are persuasive. Consequently, the objections to claims 1, 5 and 34, respectively, made in the *Non-Final Rejection*, mailed on December 5, 2008, are hereby withdrawn, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 1, 5 and 34, respectively, have been amended to overcome the objections.

## Status of Claim Rejections - 35 U.S.C. § 112, First Paragraph

Applicant's arguments, on page 9 of the *Remarks*, filed March 5, 2009, with respect to claims 4, 13-15, 19, 22, 28, 30, 33 and 55-57, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 4, 13-15, 19, 22, 28, 30, 33 and 55-57 have been canceled by applicant.

Applicant's arguments, on pages 10-11 of the *Remarks*, filed March 5, 2009, with respect to claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-36 and 54, have been fully considered, but are not persuasive. Consequently, the rejection of claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-36 and 54, made in the *Non-Final Rejection*, mailed on December 5, 2008, is maintained for the reasons of record.

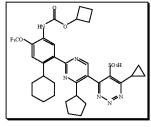
Applicant primarily argues that the law does not require the scope of enablement provided by the specification to mirror precisely the scope of protection sought by the claims. Furthermore, applicant argues that a patent application, which contains a teaching of how to make and use the invention, must be taken as enabling unless there is reason to doubt the truth of the teachings. {See *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971)}.

In response to applicant's argument that the law does not require the scope of enablement

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provided by the specification to mirror precisely the scope of protection sought by the claims, the examiner respectfully disagrees.

Currently, applicant's elected invention is directed to Group II, drawn to substituted benzenes and pharmaceutical compositions of the formula (I), where  $Y = -L-R^3$ , wherein L = -C(=O)NH or -NH(C=O); and X = -phenyl, -pyridinyl or -pyrimidinyl. Based on the guidance provided by the specification and, absent any evidence to the contrary, it is presently unclear whether a substituted benzene of the formula (I), such as 4-(2-(5-(cyclobutoxycarbonylamino)-2-



cyclohexyl-4-(trifluoromethoxy)phenyl)-4-cyclopentylpyrimidin-5-yl)-6-cyclopropyl-1,2,3-triazine-5-sulfonic acid, shown to the left, is either synthetically feasible or possesses utility in the human body as a P-38

kinase inhibitor.

The examiner requires that applicant: a) discretely indicate where the specification enables one of ordinary skill in the art to make the substituted benzene of the formula I, shown above, or a pharmaceutically acceptable composition or salt thereof; and b) discretely identify enabling disclosure that will allow one of ordinary skill in the art to use the substituted benzene of the formula I, shown above, or a pharmaceutically acceptable composition or salt thereof, as a P-38 kinase inhibitor, to overcome this rejection.

Applicant should note that the enablement requirement refers to the requirement of 35 U.S.C. § 112, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claims of the particular application or patent.

The purpose of the requirement that the specification describe the invention in such terms

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that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. A patent claim is invalid if it is not supported by an enabling disclosure.

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916)* which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. {See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)}. Accordingly, even though the statute does not use the term *undue experimentation*, it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. {See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988); and *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)}.

As a result of the *Amendments to the Claims*, filed March 5, 2009, and to clarify the record, the original rejection, made in the *Non-Final Rejection*, mailed on December 5, 2008, is amended below, in the section entitled *New Claim Rejections - 35 U.S.C.* § 112, First Paragraph, to encompass amendments to  $R^3$  of claim 1.

## Status of Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Applicant's arguments, on pages 11-12 of the *Remarks*, filed March 5, 2009, with respect to claims 4, 13-15, 19, 22, 28, 30, 33 and 55-57, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 4, 13-15, 19, 22, 28, 30, 33 and 55-57 have been canceled by applicant.

Applicant's arguments, on pages 11-12 of the *Remarks*, filed March 5, 2009, with respect to claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-36 and 54, have been fully considered, and are persuasive. Consequently, the rejections of claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-36 and 54, made in the *Non-Final Rejection*, mailed on December 5, 2008, are hereby withdrawn, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-36 and 54 have been amended to overcome the rejections.

#### Status of Claim Rejections - 35 U.S.C. § 102

Applicant's arguments, on page 12 of the *Remarks*, filed March 5, 2009, with respect to claims 4, 13-15, 22, 28, 30, 33 and 55-57, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 4, 13-15, 22, 28, 30, 33 and 55-57 have been canceled by applicant.

### Tang, et al. (WO 01/094312)

Applicant's arguments, on page 12 of the *Remarks*, filed March 5, 2009, with respect to claims 1, 12, 27, 32 and 54, have been fully considered, and are persuasive. Consequently, the rejection of claims 1, 12, 27, 32 and 54, made in the *Non-Final Rejection*, mailed on December 5, 2008, is hereby withdrawn, since, according to the *Amendments to the Claims*, filed March 5,

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2009, claims 1, 12, 27, 32 and 54 have been amended to overcome the rejection.

Angell, et al. (WO 03/093248)

have been amended to overcome the rejection.

Applicant's arguments, on page 12 of the *Remarks*, filed March 5, 2009, with respect to claims 1-3, 5, 12, 27, 29, 31, 32, 34-36 and 54, have been fully considered, and are persuasive. Consequently, the rejection of claims 1-3, 5, 12, 27, 29, 31, 32, 34-36 and 54, made in the *Non-Final Rejection*, mailed on December 5, 2008, is hereby withdrawn, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 1-3, 5, 12, 27, 29, 31, 32, 34-36 and 54

Status of Claim Rejections - 35 U.S.C. § 103

Applicant's arguments, on page 12 of the *Remarks*, filed March 5, 2009, with respect to claims 4, 13-15, 28, 30, 33, 55 and 56, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 4, 13-15, 28, 30, 33, 55 and 56 have been canceled by applicant.

Applicant's arguments, on page 12 of the *Remarks*, filed March 5, 2009, with respect to claims 1-3, 5, 12, 27, 29, 31, 32, 34-37 and 54, have been fully considered, and are persuasive. Consequently, the rejection of claims 1-3, 5, 12, 27, 29, 31, 32, 34-37 and 54, made in the *Non-Final Rejection*, mailed on December 5, 2008, is hereby withdrawn, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 1-3, 5, 12, 27, 29, 31, 32, 34-37 and 54 have been amended to overcome the rejection.

Status of Claim Rejections - Obviousness-type Double Patenting

Applicant's arguments, on page 13 of the Remarks, filed March 5, 2009, with respect to

claims 4, 13-15, 19, 22, 28, 30, 33 and 55-57, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed March 5, 2009, claims 4, 13-15, 19, 22, 28, 30, 33 and 55-57 have been canceled by applicant.

Applicant's arguments, on page 13 of the *Remarks*, filed March 5, 2009, with respect to claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-37 and 54, have been fully considered, but are not persuasive. Consequently, the rejection of claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-37 and 54, made in the *Non-Final Rejection*, mailed on December 5, 2008, is maintained for the reasons of record.

In accordance with MPEP § 804.I.B, the provisional obviousness-type double patenting rejection will be maintained until there are either no longer any conflicting claims or the double patenting rejection is the only remaining rejection in at least one of the applications.

### New Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-36 and 54 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, where R<sup>3</sup> = -a saturated 4-7 membered monocyclic heterocyclyl or -a substituted saturated 4-7 membered monocyclic heterocyclyl, for all relevant reasons of record, including those stated in the *Non-Final Rejection*, mailed on December 5, 2008, which is hereby incorporated by reference.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 12, 20, 21, 23-27, 29, 31, 32, 34-37 and 54 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation  $R^6$  is attached to any available carbon atom of the phenyl ring B... in line 6 on p. 4. There is insufficient antecedent basis, in claim 1, for this limitation with regard to the substituted benzenes and pharmaceutical compositions of the formula (I). According to line 5 of claim 1, phenyl ring B has been canceled by applicant, with respect to the substituted benzenes and pharmaceutical compositions of the formula (I).

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation the compound of claim 1... where  $R^2$  is selected from hydrogen... in lines 1-3 of the claim. There is insufficient antecedent basis, in claim 1, for this limitation with regard to the substituted benzenes and pharmaceutical compositions of the formula (I). According to line 9 of claim 1,  $R^2$  is not recited as hydrogen, with respect to the substituted benzenes and pharmaceutical compositions of the formula (I).

Claim 23 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention.

The nomenclature *methoxybenzyl* is relative nomenclature which renders the claim indefinite. The nomenclature *methoxybenzyl* is not defined by the claims, the specification does not provide an adequate standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. *Methoxybenzyl*, as recited, consists of three different isomers - 2-methoxybenzyl, 3-methoxybenzyl and 4-methoxybenzyl, whereas the species in claim 37 recites only 4-methoxybenzyl. Thus, the substituted benzenes and pharmaceutical compositions of the formula (I) have been rendered indefinite by the use of the nomenclature methoxybenzyl.

The examiner suggests replacing *methoxybenzyl*, with 2-methoxybenzyl, 3-methoxybenzyl and/or 4-methoxybenzyl, to overcome this rejection.

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the limitation the compound of claim 1, wherein P is... in line 1 of the claim. There is insufficient antecedent basis, in claim 1, for this limitation with regard to the substituted benzenes and pharmaceutical compositions of the formula (I). According to line 5 of claim 1, P, bonded to phenyl ring B, has been canceled by applicant, with respect to the substituted benzenes and pharmaceutical compositions of the formula (I).

Claim 32 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation the compound of claim 1, wherein  $R^2$  is hydrogen in lines 1-2 of the claim. There is insufficient antecedent basis, in claim 1, for this limitation with regard to the substituted benzenes and pharmaceutical compositions of the formula (I). According to line 9 of claim 1,  $R^2$  is not recited as hydrogen, with respect to the substituted benzenes and

pharmaceutical compositions of the formula (I).

Allowable Subject Matter

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-

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5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST.

The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

would like assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/

Examiner, Art Unit 1624

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624